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## EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes
and/or additions be unacceptable to applicant, an amendment may be filed as provided
by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be
submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Titus on 9/16/2009.

The application has been amended as follows:

2. In claim 4, line 1, after "of", please delete "preventing or".

## Response to Arguments

3. Applicant's arguments, filed 6/8/2009, with respect to the rejection of claims 4 and 5 have been fully considered and are persuasive. The rejection of claims 4 and 5 under 35 USC § 103(a) has been withdrawn. In the reply filed on 6/8/2009, the Applicants cancelled claims 1 and 3; the rejection of these claims is therefore considered moot.

## Reasons for Allowance

The following is an examiner's statement of reasons for allowance: claims 4 and
 are allowable over the prior art as the prior art neither teaches or suggests the method

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of treating hot flashes or vasomotor symptoms with the claimed compound or pharmaceutically acceptable salts of the compound.

The closest prior art is the US 7,354,920 patent. The US '920 patent had previously been presented by the Applicants on the IDS (as WO 2004/018441). The US '920 patent teaches that compounds of the formula shown below are norepinephrine reuptake inhibitors, which are useful for treating a variety of disorders (Abstract; column 1, line 24-column 2, line 34; column 12, lines 1-48).

Where X=O; Rz=H, etc.; Rx=H; Ry=H, etc.; Y=OH, etc.; Ar<sub>1</sub>=phenyl ring substituted with halo and O(C<sub>1-4</sub> alkyl); Ar<sub>2</sub>=substituted phenyl or heteroaryl ring. While the compounds disclosed in the US '920 patent share a core structure with the instantly claimed compound, the instantly claimed compound has a saturated tetrahydropyran ring in place of the Ar<sub>2</sub> position of the core structure shown above. There is no suggestion or teaching from the prior art which would lead one of ordinary skill in the art to modify this position from a substituted phenyl or heteroaryl ring to the saturated tetrahydropyran ring.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Conclusion

Claims 4 and 5 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/ Supervisory Patent Examiner, Art Unit 1617